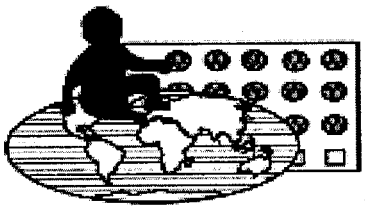

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 2, No. 1

February 2006

IINTRODUCTION

The Anti-*Toxoplasma* Antibodies (IgM and IgG) pilot proficiency testing (PT) program is a new program initiated in 2005. This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 1, 2006. The attached tables provide the certification profiles for the distributed specimens, the verification of your reported data, the statistical analysis of the quantitative data, and the frequency distributions summary for expected interpretations. We distribute this PT report to all participants, state laboratory directors, and program colleagues by request.

On January 9, 2006, a panel of five unknown dried-blood-spot (DBS) specimens prepared from human serum positive for exposure to *Toxoplasma gondii* was distributed to 2 laboratories in the United States and 8 laboratories in other countries.

PARTICIPANTS' RESULTS

We processed data from 7 participants. Laboratories were asked to report IgM screening results in IU/mL blood or Absorbance (OD). For the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

Four laboratories reported using AutoDelfia to measure anti-*Toxoplasma* IgM, 1 used Delfia and 2 reported using "other" (Bio-Rad Quantase enzyme-linked immunoassay (EIA) or an In-house EIA). The expected anti-*Toxoplasma* IgM values were based on CDC assayed values. Overall statistics from the AutoDelfia and Delfia methods were combined so as not to identify an individual laboratory. Results in OD units for the EIA method could not be combined with units for the Delfia methods and were not included in the summary statistics.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. For participants that have provided us with their anti-*Toxoplasma* IgM cutoff value, we applied that cutoff in our final appraisal of the error judgment. Overall, participants reported no false-positive interpretations and no false-negative interpretations. The mean and mode cutoffs for AutoDelfia and Delfia participants were 7.0 and 4.0 IU/mL blood, respectively.

Participants were asked to confirm specimens that screened above their cutoff for sorting test results that were *Toxoplasma* antibody reactive from those that were *Toxoplasma* antibody non-reactive. Two laboratories reported using an immunosorbent agglutination assay (ISAGA) as a secondary screening or a confirmatory test and 1 laboratory reported using an In-house indirect EIA for IgG.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-*Toxoplamsa* antibodies pilot PT specimens on April 3, 2006.

CDC/APHL

This program is cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL).

Direct inquiries to:
Centers for Disease Control and Preventtion (CDC)
4770 Buford Highway, NE, MS/F43
Atlanta, GA 30341-3724

Phone : 770-488-7945
FAX: 770-488-4255
E-mail: JMei@cdc.gov

Editor : Joanne Mei
Production: Connie Singleton

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-*TOXOPLASMA* ANTIBODIES

QUARTER I - FEBRUARY 2006

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 16T1	Specimen 16T2	Specimen 16T3	Specimen 16T4	Specimen 16T5
Anti-*Toxoplasma* Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	8.6 ± 17.1	287.3 ± 31.4	0	3.8 ± 7.6	169.0 ± 19.5

EXPECTED INTERPRETATIONS

Interpretation	Specimen 16T1	Specimen 16T2	Specimen 16T3	Specimen 16T4	Specimen 16T5
Toxoplasma Antibodies	1	2	1	1	2

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive NE = clinical assessment not evaluated

DATA VERIFICATION

Analyte	Specimen 16T1		Specimen 16T2		Specimen 16T3		Specimen 16T4		Specimen 16T5	
	Result	Code	Result	Code	Result	Code	Result	Code	Result	Code
Anti-*Toxoplasma* antibodies (IU/mL blood)										

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive NE = clinical assessment not evaluated

Reviewer's Comments

EVALUATION:

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA Antibodies

QUARTER I - FEBRUARY 2006

OVERALL STATISTICS – IgM
SCREENING RESULTS

Specimen	N*	Outliers**	Mean	UL (95%)	LL (95%)
16T1	4	0	0	0	0
16T2	4	0	304.5	420.6	188.4
16T3	4	0	0	0	0
16T4	4	0	3.6	16.1	-8.9
16T5	4	0	162.4	239.2	85.6

* Analytical results represent values from Delfia and AutoDelfia methods.
** Outliers are not included in N. UL = upper limit LL = lower limit

FREQUENCY DISTRIBUTION OF PARTICIPANTS' INTERPRETATIONS*
SCREENING RESULTS

Specimen	*Toxoplasma* antibody non-reactive	*Toxoplasma* antibody reactive
16T1	7	0
16T2	0	7
16T3	7	0
16T4	6	1
16T5	0	7

*All Methods

FREQUENCY DISTRIBUTION OF PARTICIPANTS' INTERPRETATIONS*
CONFIRMATORY RESULTS

Specimen	*Toxoplasma* antibody non-reactive	*Toxoplasma* antibody reactive
16T1	3	0
16T2	0	3
16T3	3	0
16T4	3	0
16T5	0	3

* One of three participants reported confirmatory results for IgG.

This *NEWBORN SCREENING QUALITY ASSURANCE PROGRAM* report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.**

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director
Julie Louise Gerberding, M.D., M.P.H.
Director
National Center for Environmental Health
Howard Frumkin, M.D., Dr.P.H., M.P.H.
Director
Division of Laboratory Sciences
Eric J. Sampson, Ph.D.
Chief
Newborn Screening Branch
W. Harry Hannon, Ph.D.

Contributors:
Barbara W. Adam
Carol Bell
Paul Dantonio
Marie C. Earley, Ph.D.
F. Hugh Gardner
Sherri Hall
L. Omar Henderson, Ph.D.
Lisa Kalman, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Elizabeth McCown
Joanne Mei, Ph.D.
Nancy Meredith
Hetal Patel
Jarad Schiffer
Anand Swamy, Ph.D.
Robert Vogt, Ph.D.
Yingtao Zhou

Production:
Sarah Brown
Felicia Manning
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
WASHINGTON, DC 20036-3320

President
Katherine Kelley, Dr.P.H.
Chairman, Newborn Screening and Genetics in Public Health Committee
William Becker, D.O., M.P.H.
Chairman, Newborn Screening Quality Assurance Subcommittee
John Sherwin, Ph.D.

INQUIRIES TO:

Joanne Mei, Editor • *Centers for Disease Control and Prevention (CDC)*
Newborn Screening Quality Assurance Program • *Mailstop F-43*
4770 Buford Highway, N.E. • *Atlanta, GA 30341-3724*
Phone (770) 488-4582 • *FAX (770) 488-4255* • *E-mail: JMei@cdc.gov*